REMARKS

Claims 1 through 16 and 18 through 38 are pending. Claim 17 was previously canceled. No amendments other than the Preliminary Amendment have earlier been made herein.

I. OBJECTIONS

Applicant sincerely appreciates the Examiner's careful scrutiny of the claims and the noted objection of Claims 7 and 8 improperly depending from Claim 1 rather than from Claim 6. Applicant has amended Claims 7 and 8 to suitably reflect the noted dependency.

II REJECTIONS UNDER 35 U.S.C. § 103

Claims 1 through 16 and 18 through 38 stand rejected under § 103(a) as being unpatentable over Breznock (2003/0018309) in view of Shea (4,813,941). Again, Applicant would like to summarize its position on non-obviousness before proceeding to the details.

A. BASES FOR THE OBVIOUSNESS REJECTION AND APPLICANT'S POSITIONS

i. Trocar with Stylet and Point for Puncturing the Body

The Office states, "Breznock discloses applicant's basic inventive concept of an apparatus for treating pneumothorax and/or hemothorax, substantially as claimed with the exception of an adhesively coated tab configured to secure the hub of the device to the skin. Shea (4,813,941) shows this feature to be old in the medical art. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching of Breznock to add the adhesive strips (column 4 lines 4-6) of Shea for the purpose of securing the hub of the device to the skin of the body cavity.

"Regarding claim 1, Breznock discloses a trocar with stylet and point for puncturing the body (fig 3A) and stopper (fig 3B); he also discloses a tube with lumen to receive stylet with

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open-ended portion and at least one fluid opening (fig 3B); he also demonstrates a hub and one-way valve continuous with lumens of tube and hub (fig 5A)."

* * * *

"Claims 21 and 22 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Breznock in view of Shea. Regarding claim 21, Breznock discloses a tube engaging a stylet, the tube having lumen with proximal and distal ports (fig 3B), a hub with proximal and distal face, the hub being attached to the tube, the lumen configured to form a passage for fluid continuous with tube lumen and dimensioned to receive a portion of stopper on stylet, in sealing engagement with tube lumen (3B), a one way valve in engagement with the hub distal face , the one-way valve configured so that the lumen is continuous with the passage hub lumen and tube lumen (3B). Shea (4,813,941) teaches an adhesive tab configured to draw and hold the hub in sealing engagement with the skin (column 4 lines 4-6). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching of Breznock to add the adhesive strips (column 4 lines 4-6) of Shea for the purpose of securing the hub of the device to the skin of the body cavity."

ii. Applicant's Position

a. Requirement Of Cooperation Between Intracorporal And a Slideable Extracorporal Fixation Devices Teaches Away From Adhesive Fixation

The Office states, "Breznock discloses applicant's basic inventive concept of an apparatus for treating pneumothorax and/or hemothorax, substantially as claimed ***with the exception of an adhesively coated tab configured to secure the hub of the device to the skin***." (Present Office Action at 4 (emphasis added).) Breznock teaches both an intracorporal (ref. 18, Fig. 1) and an extracorporal fixation device (ref. 16, Fig. 1) to affix the lumen to the body of the patient. (Breznock ¶0029, for example).

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However, the "extracorporal fixation device" that the Office now relies upon teaches away from the claimed adhesive hub, which is defined as "enabled once the catheter 10 is in place in the patient's chest. The extracorporeal fixation device 16 is located outside the chest and is disabled to allow the fixation device 16 to slide over the exterior of the catheter 10, into place, against or close to the patient's skin. The extracorporeal fixation device 16 is enabled and forcibly stops sliding, preventing the chest drainage tube 10 from inadvertently being pushed farther into the patient's chest." (Breznock ¶0042)

It is therefore impossible that "extracorporal fixation device" is allowed to slide over the exterior of the catheter, could be a hub coupled with said open-ended distal end portion [of the catheter tube]. (Id.)

Consequently, the Office's argument that the hub is the extracorporal fixation device, is mistaken.

In fact, as explained, "extracorporal fixation device" leads away from a fixed hub. That mistake, therefore, completely undercuts any chain of reasoning supporting the Office's conclusions that the slideably configured extracorporal fixation device would (1) result in the instant products and (2) require no teaching of "at least one adhesively coated tab attached to said hub and configured to sealingly secure the hub of said device to a skin of a body cavity." (Claim 1).

Further, the Office seeks to modify Breznock to remove the presence of the intracorporal fixation device (ref. 18, Fig. 1) that works in cooperation with the extracorporal fixation device to fix the Breznock cather into the body cavity. "When the desired location on the catheter 10 is reached, the lock is closed and the extracorporeal fixation device 16 engages the catheter 10 with enough force to make dislodgement of the fixation device 16 relative to the cannula or catheter 10 difficult, but with insufficient force to crimp or restrict the catheter 10 or the lumens 32,34,36. The clip 16 is considerably larger than the diameter of the catheter 10 and the incision in the

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chest and, preferably has atraumatic rounded edges where it contacts the patient." (Breznock ¶0043).

However, the cooperation between the intracorporal fixation device and the extracoporal fixation device teaches away from adhesive fixation of the hub and therefore the catheter to the exterior of the body of the patient.

Accordingly, one of ordinary skill in the art would not have been motivated to use Shea to modify Breznock.

b. There Is No Basis For The Office's Conclusion That "Adhesively Coated Tab Configured To Secure The Hub Of The Device To The Skin...Would Have Been Obvious To One Of Ordinary Skill In The Art At The Time Of Applicant's Invention...To The Skin Of The Body Cavity."

It is also respectfully submitted that it is not proper to interpret adhesive fixation is somehow preferred and thus would be the target of optimization. In particular, the Office's statement that "adhesively coated tab configured to secure the hub of the device to the skin...would have been obvious to one of ordinary skill in the art" is not correct. (Present Office Action at 4) Adhesive fixation alone, apparently relied on by the Office, provides no basis for concluding that adhesive fixation of the catheter relative to the body exterior would have been an obvious means of fixation for a device having a balloon for sealing the catherer into a defined incision. provide any basis for concluding anything about desirability of an adhesive means of sealing a catheter into the incision.

c. Breznock Teaches Intracorporal Sealing Of The Catheter In The Incision And Does Not Focus On Extracorporal Sealing Of The Catheter To The Incision.

As properly understood, therefore, Breznock does not focus on extracorporal sealing as preferred or optimized, but rather teaches the entire possible domain of intracorporal sealing, including by means of inflation of an interior balloon. "The drainage cannula of the present

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invention includes an intracorporeal fixation or retaining device that prevents the cannula from being removed inadvertently from the patient. This intracorporeal device is, for example, an elastomeric or inelastic (i.e. angioplasty-type) balloon affixed to the exterior surface of the cannula. The balloon is passed inside the chest cavity and is inflated with sterile liquids or air to prevent withdrawal through the hole or wound in the chest wall." (Breznock ¶0016)

In summary, none of "intracorporal fixation" "angioplasty type balloons" or "inelastic" intracorporal fixation leads to the claimed invention relying upon adhesive fixation.

c. Neither Of Breznock And Shea Would Have Motivated One Of Ordinary Skill In The Art To Adhesively Fixate A Hub Fixedly Coupled To A Cather To An Exterior Of A Patient.

As understood, the Office's argument Breznock and Shea show that the product taught by Breznock has a well known track record of clinical utility.

Because of that known utility, one of ordinary skill would be motivated to continue optimization of the product taught by Breznock to develop the product.

Optimization of the process, including substitution of sealing adhesive fixation to eliminate the need for the cooperation of intracorporal fixation device and the slideable extracorporal fixation device would appear to result in the instant product.

As explained above, however, a teaching of "intracorporal fixation device" or "extracorporal fixation device" slideably attached teaches away from the degree of sealingly adhesive fixation of a hub coupled to the catheter. There is thus no basis for the Office's conclusions that clinical utility would lead to optimization of the Breznock product and result in the claimed sealingly adhesive strips.

In Shea, the teaching of adhesive strips is specifically to strips that stand proud from the surface of the patient's body and not in sealing adhesion. At Col. 3, Lines 65 to 68, the purpose of the strips is to drape over the wings for adhesion. As illustrate in FIG. 6, no sealing is shown or taught. It is therefore irrelevant whether or not the "at least one adhesively coated tab attached

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to said hub and configured to sealingly secure the hub of said device to a skin of a body cavity" claimed are the adhesive taught by Shea.

(Present Office Action at 9 and 18.) None of those documents discloses anything about adhesive tabs configured to seal. Furthermore, in the absence of such information, none of those documents provides any clue or motivation that would lead to a dual-sided adhesion necessary to achieve the sealing adhesion of the hub to the skin of the body cavity.

C. CONCLUSION: NO CLAIM IS RENDERED OBVIOUS IN VIEW OF THE REFERENCES OF RECORD

For the reasons discussed above, it is respectfully submitted that the references of record are insufficient to establish a *prima facie* case of obviousness. Reconsideration and withdrawal of the §103(a) rejections are therefore respectfully requested.

CONCLUSION

In summary, the pending claims are novel and none of the art of record, taken alone or together, renders the claims prima facie obvious. All the pending claims are in condition for allowance, and issuance of a notice of allowance is respectfully requested.

The applicant respectfully requests that any issues or concerns of the Examiner continue to be addressed to applicant's attorney of record, the undersigned.

Respectfully submitted,

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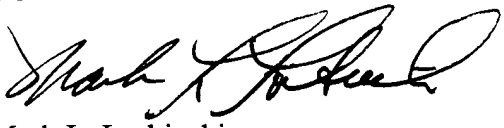

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I hereby certify that this communication is being deposited with the United States Postal Service via first class mail under 37 C.F.R. § 1.08 on the date indicated below addressed to: MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

25 November 2005 — Mark L. Lorbiecki
Date of Deposit

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